510(k) SUMMARY

JUL 18 2008

CADD™ Medication Cassette Reservoir

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	David H. Short Director Regulatory Affairs and Design Assurance
Common/Usual Name:	Medication Cassette Reservoir
Proprietary Name:	CADD™ Medication Cassette Reservoir
Equivalence Device Comparison:	CADD™ Medication Cassette Reservoir with Flow Stop Flexible Medication Reservoir

II. DEVICE DESCRIPTION

The CADD™ Medication Cassette Reservoir with Flow Stop feature is a modification to the current CADD™ Medication Cassette Reservoir with Flow Stop. The modification incorporates a 250 mL reservoir and a two-part housing assembly. It is provided with a medication bag and pump tube, extension tube, pressure plate with Flow Stop feature, rear housing, clamp and leur assembled with the cover set into the rear housing assembly but not snapped together. This two-part housing design is intended to allow manipulation of the medication bag for removal of air bubbles prior to permanently snapping the housing together.

III. INTENDED USE OF THE DEVICE

The CADD™ Medication Reservoirs are designed for use with the CADD® pumps (except CADD® Micro, CADD-MS™ 3, and CADD TPN®) for medication delivery.

IV. DEVICE COMPARISON

The CADD™ Medication Cassette Reservoir with Flow Stop is similar in design, function, and intended use to the predecessor CADD™ Medication Cassette Reservoir with Flow Stop, K040636. These sets are identical except for size and

assembly method of the housing prior to use with the pump. The reservoir housing for the predecessor device, 50 mL and 100 mL capacity, is ultrasonically welded to the pressure plate, whereas the 250 mL reservoir housing is a two-piece design that is snapped together by the clinician prior to attachment to the pump.

V. SUMMARY OF STUDIES

A. Functional Testing

The CADD™ Medication Cassette Reservoir with Flow Stop was subjected to verification and validation testing. All tests performed demonstrate that the CADD™ Medication Cassette Reservoir with Flow Stop meets the acceptance criteria for the safety and performance requirements set by the CADD™ Medication Cassette Reservoir with Flow Stop specifications.

B. Clinical Studies

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the CADD™ Medication Cassette Reservoir with Flow Stop.

C. Conclusions Drawn from the Studies

Based upon the information provided, CADD™ Medication Cassette Reservoir with Flow Stop is safe, effective and performs to established specifications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2008

Mr. David H Short
Director Regulatory Affairs and Design Assurance
Smiths Medical Md, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K081156
Trade/Device Name: CADD Medication Cassette Reservoir
~~Regulation Number: 880.5440~~
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 22, 2008
Received: April 23, 2008

Dear Mr. Short:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket ~~approval application (PMA)~~. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081156

SMITHS MEDICAL MD, INC.
510(k) Premarket Notification
CADD™ Medication Cassette Reservoir

Indications for Use

510(k) Number: _____

Device Name: **CADD™ Medication Cassette Reservoir**

Indications for Use:

"The CADD™ Medication Cassette reservoirs are intended for the delivery of medications and fluids for subcutaneous, intramuscular, intravenous, intra-arterial, intraperitoneal, or intraspinal infusion."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for SDW 7/18/08

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081156